## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Plaintiff,

v.

Civil Action No. 2:15-cv-06133-WB

ELI LILLY AND COMPANY, IMCLONE LLC, and BRISTOL-MYERS SQUIBB COMPANY,

Defendants.

## MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS IMPROPER MULTIPLE DEPENDENT CLAIMS 32–40 OF U.S. PATENT NO. 7,625,558

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants Eli Lilly and Company, ImClone LLC, and Bristol-Myers Squibb Company (collectively, "Defendants") respectfully move to dismiss Plaintiff Trustees of the University of Pennsylvania's allegations that Defendants infringe or have infringed claims 32–40 of U.S. Patent No. 7,625,558 ("the '558 patent"). Claims 32–40 are improper multiple dependent claims and are, therefore, facially invalid. Because it is impossible to infringe an invalid patent claim, Plaintiff has not—indeed cannot—allege any set of facts under which Defendants would be liable for infringement of these claims.

## **BACKGROUND**

The '558 patent, titled "Compositions and Methods of Treating Tumors," claims methods for treating certain types of cancer using a combination of antibodies and radiation therapy. The patent contains 41 claims, including six independent claims and 35 dependent claims.

Claims 28–36, 40, and 41 are multiple dependent claims, meaning that they depend from more than one claim. Claim 28, for example, recites:

28. **The method according to claim 26 or 27**, wherein the radiation is administered beginning within 1 to 10 hours after administration of the pharmaceutical composition.

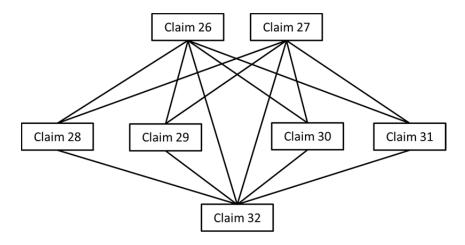
'558 patent, claim 28 (emphasis added). Claim 28 therefore depends from both claim 26 and claim 27.

Claims 32–36, 40, and 41 are *improper* multiple dependent claims, meaning that they are (1) multiple dependent claims that (2) depend from claims that are, themselves, multiply dependent. As an example, claim 32 recites:

32. The method according to any one of claims 26 to 31 wherein the radiation is administered as multiple doses.

'558 patent, claim 32 (emphasis added). That is, claim 32 is a multiple dependent claim that depends from claims 26, 27, 28, 29, 30, and 31. Claim 32 is an *improper* multiple dependent claim because it depends, in part, from claim 28 which is, itself, a multiple dependent claim.<sup>1</sup>

The following diagram illustrates the chain of dependencies for claim 32.



<sup>&</sup>lt;sup>1</sup> A claim is an improper multiple dependent claim if *any* of its parent claims are multiple dependent claims. In claim 32, four of its parents (claims 28–31) are multiple dependent claims.

At the top of the diagram are independent claims 26 and 27. The claims in the middle row, claims 28–31, are (proper) multiple dependent claims, because they depend only from the independent claims. At the bottom is improper multiple dependent claim 32, which depends from all of the claims above it.

Claims 33–36, 40, and 41 are improper for exactly the same reason as claim 32. Each one is a multiple dependent claim that depends from, among other claims, multiple dependent claim 28.

Claims 37–39 are also improper multiple dependent claims because each one depends from claim 36, which is, itself, an improper multiple dependent claim.

On November 13, 2015, Plaintiff filed this patent infringement action alleging that Defendants indirectly infringe claims 1–7, 9–12, 14, 16, 17, 19–30, and 32–40 of the '558 patent by "encouraging, instructing, and inducing other" to use Defendants' Erbitux<sup>®</sup> product. (D.I. 1, Complaint, ¶¶ 46, 52, 58.) In particular, Plaintiff has accused Defendants of infringing improper multiple dependent claims 32–40. (*Id.*)

Prior to filing this motion, Defendants asked Plaintiff to withdraw claims 32–40. Plaintiff refused.

## **ARGUMENT**

Dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is appropriate when "accepting the well-pled allegations of the complaint as true, and drawing all reasonable inferences in the light most favorable to plaintiff, it appears that a plaintiff could prove no set of facts that would entitle it to relief." *Jaramillo v. Experian Information Solutions, Inc.*, 155 F. Supp. 2d 356, 358 (E.D. Pa. 2001).

When there are no disputed questions of fact, it is appropriate for a Court to decide the validity of a patent claim on a motion to dismiss. For example, whether a patent claim is

directed to patent eligible subject matter under 35 U.S.C. § 101 is a "threshold" inquiry. *Bilski v. Kappos*, 561 U.S. 593, 601–02 (2010). District courts routinely decide the validity of patents under Section 101 on motions to dismiss. *See, e.g., Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526–27 (D. Del. 2014); *Wireless Media Innovations, LLC v. Global Terminal & Container Servs., LLC*, 100 F. Supp. 3d 405, 410 (D.N.J. 2015); *Priceplay.com, Inc. v. AOL Adver., Inc.*, 83 F. Supp. 3d 577, 580 (D. Del. 2015). The Federal Circuit regularly affirms those dismissals. *See, e.g., Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359 (Fed. Cir. 2015). Moreover, the ability to decide patent validity at the outset of a case is not limited to issues arising under Section 101. District courts may also decide, for example, whether a patent claim is indefinite under Section 112 as part of a motion for judgment on the pleadings. *See, e.g., WAGO Verwaltungsgesellschaft mbH v. Rockwell Automation*, No. 1:11-cv-00756, 2012 WL 775683, at \*4–5 (N.D. Ohio March 7, 2012).

\* \* \* \* \*

Improper multiple dependent claims are invalid as a matter of law. Section 112 of Title 35 defines a variety of requirements that every patent, and every patent claim, must satisfy. A claim that "fail[s] to comply with any requirement of Section[] 112" is invalid. 35 U.S.C. § 282.<sup>2</sup> The Federal Circuit has explained that "any requirement" really means "any requirement." *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006) (noting that the Patent Act's "overall statutory scheme . . . requires applicants to satisfy certain

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<sup>&</sup>lt;sup>2</sup> U.S. Patent Application 10/100,952, which issued as the '558 patent, was filed before the enactment of the America Invents Act ("AIA"), Pub. L. No. 122-29, on September 16, 2012. While none of the provisions of the AIA affects the disposition of this motion, all citations to Title 35 in this motion refer to the version in effect before the enactment of the AIA.

requirements before obtaining a patent, some of which are more procedural or technical than others"). Section 112 expressly prohibits multiple dependent claims that depend from other multiple dependent claims. 35 U.S.C. § 112 ¶ 5 ("A multiple dependent claim shall not serve as a basis for any other multiple dependent claim."). Therefore, an improper multiple dependent claim is invalid for failing to satisfy 35 U.S.C. § 112 ¶ 5.

This requirement of Section 112 is reflected in the Manual of Patent Examining

Procedure ("M.P.E.P."), which contains the rules and regulations of the United States Patent and

Trademark Office ("USPTO") governing practice before the USPTO.<sup>3</sup> According to the

M.P.E.P., improper multiple dependent claims violate 35 U.S.C. § 112 ¶ 5 and should not be

allowed. *See* M.P.E.P. § 608.01(n) ("A multiple dependent claim which depends from another

multiple dependent claim should be objected to by using form paragraph 7.45."). The M.P.E.P.

also provides an example of such an improper claim:

A gadget as in claim 5 (claim 5 is a multiple dependent claim) or claim 7, in which ---

*Id.* Finally, the M.P.E.P. explains that any claim that depends from an improper multiple dependent claim is improper and should therefore be objected to by the patent examiner. *Id.* ("Any claim depending from an improper multiple dependent claim will also be considered to be improper."); *id.* ("Claim 8 is improper since it depends from an improper claim.").

\* \* \* \* \*

Section 112 is clear and unambiguous—improper multiple dependent claims are invalid.

The claims at issue in this motion, claims 32–40 of the '558 patent, are in precisely the form

<sup>&</sup>lt;sup>3</sup> The regulations codified in the M.P.E.P. were promulgated under 35 U.S.C. § 2(b)(2)(A), which authorizes the USPTO to "establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings" at the USPTO. The regulations in the M.P.E.P., and all amendments thereto, are also published in the Federal Register. *See* M.P.E.P, Introduction.

prohibited by Section 112 and the M.P.E.P. Claim 32, for example, is a multiple dependent claim that depends from "any one of claims 26 to 31." '558 patent, claim 32. But claim 28, from which claim 32 depends, is itself a multiple dependent claim. *See id.*, claim 28 ("The method according to claim 26 or 27, . . . ."). Claim 32 is therefore an improper multiple dependent claim, invalid under 35 U.S.C. § 112 ¶ 5. Claims 33–36 and 40 suffer from the exact same flaw. Claims 37–39 depend from improper multiple dependent claim 36 and are therefore invalid as well. *See, e.g.*, M.P.E.P. § 608.01(n).

The fact that claims 32–40 are improper multiple dependent claims is apparent from the face of the '558 patent. The failure of the claims to comply with Section 112 does not depend on claim construction, the details of the patent specification, the knowledge of a person of skill in the art, or an assessment of the prior art. Instead, it follows directly from the form of the claims. Indeed, the defect in the claims is evident from the preambles to the claims alone, *i.e.* everything up to the word "wherein":

- 28. The method according to **claim 26 or 27**, wherein . . .
- 32. The method according to **any one of claims 26 to 31** wherein . . . '558 patent, claims 28, 32. It is indisputable, from the preambles alone, that claim 32 is a multiple dependent claim that depends, in part, from multiple dependent claim 28. The immediate corollary, that claim 32 is invalid, follows as a matter of law.

\* \* \* \* \*

An invalid patent claim cannot be infringed. *See, e.g., Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."). Section 282 of the Patent Act makes the invalidity of a patent claim—including invalidity under Section 112—a complete defense to patent infringement. 35 U.S.C. § 282(3). Because claims 32–40 of the '558 patent are invalid, there are no facts that Plaintiff could

possibly plead that would make Defendants liable for infringing these improper multiple dependent claims.

Defendants' motion to dismiss improper multiple dependent claims 32–40 should therefore be granted.

Dated: January 15, 2016

Respectfully submitted.

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